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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,969	01/04/2002	John Manfredi	1418.03	1729

26698 7590 07/14/2004  
MYRIAD GENETICS INC.  
LEGAL DEPARTMENT  
320 WAKARA WAY  
SALT LAKE CITY, UT 84108

EXAMINER

BURKHART, MICHAEL D

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

519 -

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/040,969	MANFREDI, JOHN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael D. Burkhardt	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/04/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/1/02 and 9/13/02</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-12 and 23), filed 4/26/2004, is acknowledged. Claims 13-22 and 24-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Priority***

Applicant's claim for domestic priority to US Application 60/259,759, filed 1/4/2001, is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 23 are rejected as being indefinite for failing to recite a positive process step that refers back to the preamble of the claim. In order for the claimed method to be definite in terms of the metes and bounds of the invention, the claim must recite a method step that provides for the results of the method as claimed. This rejection affects all dependant claims. It would be remedial to amend the claims to include the statement "thereby detecting an interaction between the first and second test agent."

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Claims 1 and 23 are rejected as being indefinite for reciting "substantially cell free environment." This limitation is indefinite because it is unclear what constitutes substantially cell free. The metes and bounds of the claimed subject matter are unclear. This rejection affects all dependant claims.

Claim 12 is rejected as being indefinite for reciting "derivatives thereof." This limitation is indefinite because it is unclear how close to the original the derivatives might be. The metes and bounds of the claimed subject matter are unclear.

Claim 23 is rejected because of the following informalities: "capable interfering" should be replaced with "capable of interfering" in the preamble. Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6,551,786 ('786 hereafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the instant claim is rendered obvious by the method

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recited in '786. The instant claim recites an *in vitro* method to detect compounds capable of interfering with an interaction between a first and second test agent. This is done by providing two fusion constructs comprising non-interacting N- or C- inteins, the test agents, and inactive reporter(s). If the test agents interact, the inactive reporter is activated by protein splicing (courtesy of the inteins). The fusion constructs are allowed to interact in the presence of test compounds, and the activity of the reporter is measured. The '786 patent recites the same *in vitro* method except for the non-interacting limitation of the inteins. However, this limitation is inherent to the method claimed in '786, as without it the test agent interaction aspect of the method has no specificity. If interacting inteins were used in the '786 patent, they would continuously splice out the inactive reporter, producing a high level of active reporter. This would make detection of any interaction by the test agents impossible. Therefore, the claims of the '786 patent anticipate the instant claim 23.

The closest prior art is exemplified by Ozawa et al. (reference B11 of the IDS) and Ozawa et al. (reference B12 of the IDS). The Ozawa B11 reference teaches the detection of protein-protein interactions using inteins and protein splicing of the EGFP reporter protein. The Ozawa B11 reference does not teach the detection of these interactions *in vitro*.

The Ozawa B12 reference teaches the detection of protein-protein interactions using inteins and protein splicing of the luciferase reporter protein. The Ozawa B12 reference does not teach the detection of these interactions *in vitro*.

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*Allowable Subject Matter*

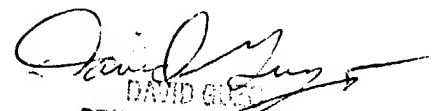
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Burkhart  
AU 1636

  
DAVID G. LEE  
PRIMARY EXAMINER